Veramyst: Product Profile 2-Page Summary

This information is provided in response to your request for information about Veramyst® (fluticasone furoate) Nasal Spray.

DISEASE: ALLERGIC RHINITIS

- Nasal allergies are one of the most prevalent and chronic diseases in the United States, affecting up to 50 million people,[1] including 10 to 30 percent of adults and up to 40 percent of children.[2]
- Allergic rhinitis has been associated with affects on patients' quality of life including fatigue and daytime sleepiness,[3,4] daily activity impairment,[5,6] reduced work productivity,[5,6,7] impaired cognitive functioning,[8,9] reduced learning abilities,[10] impaired sleep,[11] and impaired quality of life.[4]
- Allergic rhinitis is estimated to cause 3.5 million lost workdays and >2 million missed school days per year.[12]
- For adults, seasonal allergic rhinitis (SAR) is a major cause of work absenteeism and reduced productivity, resulting in nearly $4 billion annually in lost productivity,[2] and $1,000 per day per worker in lost productivity.[13]
- Approximately 14 million physician office visits each year are attributed to allergic rhinitis.[14]
- Intranasal corticosteroids (INS) reduce the inflammation that is a root cause of nasal allergies,[15] and have been proven effective for the treatment of all 4 nasal symptoms (congestion, rhinorrhea, sneezing, and nasal itching) in both SAR and perennial allergic rhinitis (PAR).[16,17]

BENEFITS OF *VERAMYST*:

- *Veramyst* is the first and only INS proven to help relieve all 4 nasal symptoms (congestion, rhinorrhea, sneezing, and nasal itching), and all 3 ocular symptoms (itching/burning, tearing/watering, redness), assessed as a secondary endpoint, in patients 12 years and older with SAR in 5 prospectively designed and replicated studies.
- *Veramyst* is approved for use in children down to 2 years of age.
- *Veramyst* has demonstrated improvement in overall disease-specific quality of life in adult and adolescent patients with SAR.
- *Veramyst* has demonstrated significant symptom improvement within 24 hours for patients with SAR. Patients with PAR experience significant symptom improvement after day 4 of treatment. Maximum benefit may take up to several days.
- *Veramyst* has a unique ergonomically designed nasal delivery device with a side actuator that releases a consistent, low volume mist thru a small short nozzle with each actuation. It does not require daily priming and the unscented, alcohol-free, aqueous formulation can be viewed through the indicator window.
- *Veramyst* is approved for once daily administration and offers a flexible dosing option based on patients' symptom control.

EFFICACY:

- *Veramyst* 110 mcg once daily produced significant improvements in reflective total nasal symptoms scores (rTNSS), morning pre-dose instantaneous total nasal symptoms scores (AM iTNSS), and reflective total ocular symptoms scores (rTOSS) compared with vehicle-placebo in three 2-week, pivotal efficacy trials in adult and adolescent patients 12 years of age and older with SAR.[18,19,20]
- *Veramyst* 110 mcg once daily produced significant improvements in rTNSS and AM iTNSS compared with vehicle-placebo in a 4-week clinical trial[21] and a 6-week clinical trial[22] in adult and adolescent patients 12 years of age and older with PAR.
- In the 4-week clinical trial in adult and adolescent patients with PAR, *Veramyst* 110 mcg once daily did not demonstrate any significant improvements in ocular symptoms compared with vehicle-placebo.[23]
- *Veramyst* 110 mcg once daily for 2 weeks significantly improved nighttime symptom score (NSS) and all other secondary nasal efficacy endpoints (daytime, nighttime, 24-hour, and iTNSS) compared with fexofenadine 180 mg once daily and compared with placebo in 2 well-controlled studies in adults and adolescents 12 years of age and older with SAR. Improvements in ocular symptoms (daytime, nighttime, 24-hour, and iTOSS) were significantly greater compared with placebo and were comparable with improvements seen with fexofenadine.[24,25]
- *Veramyst* 55 or 110 mcg once daily for 2 to 12 weeks generally produced greater improvements in rTNSS compared with vehicle-placebo in 2 pivotal efficacy trials in pediatric patients 2 to 11 years of age with SAR or PAR. rTNSS was significantly improved with the 110 mcg dose in the SAR study and with the 55 mcg dose in the PAR study.[26,27]
- *Veramyst* 110 mcg once daily produced statistically significant and clinically meaningful improvements in overall quality of life as assessed by the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) compared with vehicle-placebo in three 2-week clinical trials in adult and adolescent patients 12 years of age and older with SAR.[18,20,28]
- In the 4-week clinical trial in adult and adolescent patients with PAR, there were no statistically significant or clinically meaningful improvements in overall RQLQ between *Veramyst* and vehicle-placebo.[23]

SAFETY:

- Overall, adverse reactions to *Veramyst* were similar to vehicle-placebo and occurred with approximately the same frequency.[23]
- In clinical trials of 2 to 6 weeks, common adverse reactions in patients 12 years of age and older treated with *Veramyst* 110 mcg versus placebo were headache (9% vs. 7%), epistaxis (6% vs. 4%), pharyngolaryngeal pain (2% vs. 1%), nasal ulceration (1% vs. <1%), and back pain (1% vs. <1%).[23] Less than 3% of patients discontinued therapy because of adverse reactions. The rate of withdrawal among patients receiving *Veramyst* was similar or lower than the rate among placebo-treated patients.
- In clinical trials of 2 to 12 weeks, common adverse reactions in patients 2 to <12 years of age treated with *Veramyst* 55 mcg, 110 mcg versus placebo were headache (8%, 8%, vs. 7%), nasopharyngitis (5%, 5%, vs. 5%), epistaxis (5%, 4%, vs. 4%), pyrexia (5%, 4%, vs. 2%), pharyngolaryngeal pain (4%, 3%, vs. 3%), and cough (3%, 4%, vs. 3%).[23] Pyrexia occurred more frequently in children 2 to <6 years of age compared with children 6 to <12 years.
- Adverse reactions reported during a long-term, 52-week clinical study of adults and adolescents with PAR were similar in type and rate between treatment groups with exception of epistaxis which occurred more frequently in patients treated with *Veramyst* (123/605, 20%) than in placebo-treated patients (17/201, 8%).[29] The epistaxis tended to be more severe in patients treated with *Veramyst*, as all 17 reports

of epistaxis in the placebo-treated patients were of mild intensity, while 83, 39, and 1 of the total 123 epistaxis events in patients treated with *Veramyst* were of mild, moderate, and severe intensity, respectively. Epistaxis led to the withdrawal of 15 patients (2%) in the group receiving *Veramyst* and no subjects in the placebo group.[30] No patient experienced a nasal septal perforation during the study.[23]

INDICATION:

- *Veramyst* is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis in patients 2 years of age and older.[23]

DOSING:

- **Adults and Adolescents 12 Years of Age and Older:** Start with 110 mcg once daily administered as 2 sprays (27.5 mcg/spray) in each nostril.[23] Titrate to the minimum effective dosage to reduce the possibility of side effects. When the maximum benefit has been achieved and symptoms have been controlled, reducing the dosage to 55 mcg (1 spray in each nostril) once daily may be effective in maintaining control of allergic rhinitis symptoms.
- **Children 2 to 11 Years of Age:** Start with 55 mcg once daily administered as 1 spray (27.5 mcg/spray) in each nostril.[23] Children not adequately responding to 55 mcg may use 110 mcg (2 sprays in each nostril) once daily. Once adequate control is achieved, the dosage may be decreased to 55 mcg once daily.

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